008810-20021
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Prior Application
Examiner: Brown, M.
Art Unit: 3764

CONTINUATION APPLICATION TRANSMITTAL

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is a request for filing a continuation application pursuant to 37 C.F.R. § 1.53(b), of pending prior application:

Serial No. 08/480,904 filed June 7, 1995, by Gary K. Michelson, M.D. (inventor(s) currently of record in prior application) for METHOD FOR INSERTING FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS.

1. ☒ Enclosed is a copy of the prior application, including the oath or declaration as originally filed, or a replacement specification which does not add new matter.

2. ☒ The filing fee is calculated below:

CALCULATION OF FEES								
ITEM		TOTAL NO. OF CLAIMS		NO. OF CLAIMS OVER BASE	LG/SM $ ENTITY FEE		$ AMOUNT	$ FEE
A	TOTAL CLAIMS FEE	1	-20	0	LG=$18 SM=$9	$18	$ 0	0
B	INDEPENDENT CLAIMS FEE*	1	-3	0	LG=$78 SM=$39	$78	$ 0	0
C	SUBTOTAL – ADDITIONAL CLAIMS FEE (ADD FINAL COLUMN IN LINES A + B)							$ 0
D	MULTIPLE-DEPENDENT CLAIMS FEE				LARGE ENTITY FEE = $260 SMALL ENTITY FEE = $130			$ 0
E	BASIC FEE				LARGE ENTITY FEE = $760 SMALL ENTITY FEE = $380			$ 760 00
F	TOTAL FILING FEE (ADD TOTALS FOR LINES C, D, AND E)							$760 00
	*LIST INDEPENDENT CLAIMS 1							

3. ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Account No. 50-1066. A copy of this sheet is enclosed.

4. ☒ A check in the amount of $ 760.00 is enclosed.

5. ☒ Cancel in this application original claim(s) 2-17 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

6. ☒ Amend the specification by deleting the first two sentences on page 2 and insert before the first line the sentence:

This is a ☒ continuation ☐ division of application Serial No. 08/480,904 filed June 7, 1995.

7a. ☒ New formal drawings are enclosed.

7b. ☐ Priority of application Serial Nos.:

___ application Serial No. ___ filed ___ is claimed under 35 U.S.C. § 119.

7c. ☐ The certified copy of the priority application will be filed in prior application Serial No. ___, filed ___.

8. ☐ The prior application is assigned of record to: ___.

9. ☒ The power of attorney in the prior application is as listed on the attached copy of the declaration filed in the patent application.

a. ☒ The power appears in the original papers in the prior application.

b. ☐ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.

c. ☒ Address all future communications to the following Customer Identification Number:

22882

PATENT TRADEMARK OFFICE

Customer ID#22882
Amedeo Ferraro, Esq.
MARTIN & FERRARO LLP
14500 Avion Parkway, Suite 300
Chantilly, VA 20151-1101
703-818-3261

10a. ☐ A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered original claim in the prior application.)

10b. ☐ A separate check for $___ is enclosed to cover additional claims added by the preliminary amendment.

11. ☐ Enclosed find the following declaration(s) in support of Small Entity status for this application:

- ☐ Inventor(s)
- ☐ Individual other than inventor
- ☐ Nonprofit organization
- ☐ Small business concern

12. ☐ The statement(s) of Small Entity Status filed in the prior application is (are) still proper.

Date: October 4, 1999

Amedeo Ferraro
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A

PATENT
Attorney Docket No: 008810-20021

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Art Unit: 3764
Gary K. Michelson, M.D.	Examiner: Brown, M.
Serial No: N/A	
Filed: N/A	
For: METHOD FOR INSERTING FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS	

CERTIFICATE OF MAILING VIA U.S. EXPRESS MAIL
"Express Mail" Mailing Label No. E L399233205US
Date of Deposit: October 4, 1999

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I hereby certify that

- ☒ two copies of a Continuation Application transmittal
- ☒ True copy of prior application, and Combined Declaration and Power of Attorney as filed
- ☒ Drawing Amendment
- ☒ 6 sheets of formal drawings
- ☒ check in amount of $ 760.00 for the filing fee
- ☒ return postcard

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service with sufficient postage under 37 C.F.R. § 1.10 on the date indicated above and are addressed to:

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231.

Date: October 4, 1999

Lisa K. Robbins
Name of person mailing papers

Lisa K. Robbins
Signature

14500 Avion Parkway, Suite 300
Chantilly, VA 20151-1101
TEL: 703-818-3276

BACKGROUND OF THE INVENTION

Related Applications

This application is a continuation in part of copending United States application Serial No. 08/396,414 filed on February 27, 1995 which is a continuation-in-part of United States application Serial No. 08/074,781 filed on June 10, 1993, which is a continuation in part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional of application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247 all of which are incorporated herein by reference.

This application is also a continuation-in-part of United States application Serial No. 08/390,131 entitled Interbody Spinal Fusion Implants filed on February 17, 1995. This application is also a continuation in part of design patent Application Serial No. 29/023,623 entitled Spinal Distractor filed on October 3, 1994.

Field of the Invention

The present invention relates generally to a method for inserting interbody spinal fusion implants, and in particular to a method for inserting spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine

are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Michelson, in U.S. Patent Application Serial No. 08/396,414, entitled APPARATUS AND METHOD OF INSERTING SPINAL IMPLANTS, teaches a method for restoring the anatomical lordosis of the spine while performing the interbody fusion procedure. While this has been a significant advance over prior methods, it has nevertheless been associated with a sometimes less than desirable consequence, that being the uneven removal of bone from each of the adjacent vertebrae relative to the vertebral endplates adjacent the disc space.

Therefore, there exists a need for spinal fusion implants and instrumentation that permits for the uniform depth of bone removal from each of the adjacent vertebrae while restoring anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a method for inserting a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration to achieve a desired anatomical lordosis of the spine. In the preferred embodiment of the method of the present invention, the spinal fusion implants being inserted have an outer locus in which at least some of the points of the implant comprise a partially or fully frusto-conical shape substantially along the portion of the implant in contact with the adjacent vertebrae of the spine and have an insertion end and a trailing end. The spinal fusion implants may be further modified so that while the upper and lower surfaces are portions of a frusto-cone, or a cylinder at least one side portion may be truncated to form a planar surface that is parallel to the central longitudinal axis of the implant to form straight walls. These implants may have a more tapered aspect at the insertion end of the implant to facilitate insertion. The spinal fusion implants of the

present invention may be relatively solid and/or porous and/or hollow, and may have surface roughenings to promote bone ingrowth and stability.

In the preferred method of the present invention, the diseased disc between two vertebrae is at least partially removed. The two vertebrae adjacent the diseased disc are then optimally distracted and placed in the desired amount of lordosis by any of a number of well known means including, but not limited to, those means that distract the vertebral bodies by engaging screws placed into the anterior aspect of the vertebral bodies, and disc space distractors that are placed from the anterior aspect of the spine into the disc space and are then used to urge the vertebral endplates away from each other and into lordosis. When the correct amount of distraction and lordosis have been achieved at the affected disc level, then a frusto-conical space is created from anterior to posterior between the adjacent vertebrae. The frusto-conical space that is created is greater in diameter than the disc space height, such that some bone is removed from each of the adjacent vertebrae. The created space is generally frusto-conical in shape, being greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

In an alternative method of implant insertion, the use of at least partially frusto-conical interbody spinal fusion implants allows for the creation of lordosis by the implant itself where none is present to begin with. The disc space which in the preferred circumstance would be fully distracted but need not be, but lacking lordosis, could have a bore drilled across that space such that equal arcs of bone are removed from each of the adjacent vertebrae using a drill or bone milling device capable of producing a cylindrical bore. The vertebrae, whether distracted from each other or not, are essentially lacking the full restoration of lordosis. The use of the substantially cylindrical bone drill provides for the removal of a generally uniform thickness of bone from each of the adjacent vertebrae from anterior to posterior. The insertion of a frusto-conical implant, having a larger diameter

at its trailing edge than at its leading edge, then forces the anterior aspects of the adjacent vertebrae apart more so than the posterior aspects where the diameter is lesser. This utilizes the implant to produce the desired lordosis.

To further assist incorporation into the spinal fusion bone mass, the spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes, may pass either into or through the implant and may or may not intersect. The spinal fusion implants of the present invention may have at least one chamber which may be in communication through at least one opening to the surface of the implant. Said chamber may have at least one access opening for loading the chamber with fusion promoting substances. The access opening may be capable of being closed with a cap or similar means. Still further, a variety of surface irregularities may be employed to increase implant stability and implant surface area, and/or for the purpose of advancing the spinal fusion implant into the fusion site such as a thread. The exterior of the spinal fusion implant of the present invention may have wholly or in part, a rough finish, knurling, forward facing ratchetings, threads or other surface irregularities sufficient to achieve the purpose described.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape, those that taper from the leading edge to the trailing edge they are easy to introduce and easy to fully insert into the spinal segment to be fused. In the preferred embodiment, where the leading edge of the implant is larger than the trailing edge, the implant utilizes a tapered forward portion and an increasing thread height relative to the body from the leading edge to the trailing edge to facilitate insertion.

2. The shape of the implants of the present invention is consistent with the shape of the disc, which the implants at least in part replace, wherein the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.

3. The spinal fusion implants of the present invention allow for a minimal and uniform removal of bone from the vertebrae adjacent the disc space while still providing for an interbody fusion in lordosis when properly inserted.

4. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics or combination sufficient for the intended purpose. Further, the spinal fusion implants of the present invention may be made of a solid material, a mesh-like material, a porous material and may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or be loaded with, composed of, treated or coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, to make them bioactive for the purpose of stimulating spinal fusion. The implants of the present invention may be wholly or in part bioabsorbable.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a method for inserting frusto-conical spinal fusion implants into the spine;

It is yet another object of the present invention to provide a method for inserting frusto-conical spinal fusion implants that are capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

It is yet another object of the present invention to provide a method for inserting frusto-conical spinal fusion implants that is capable of providing stability between adjacent vertebrae when inserted;

It is further another object of the present invention to provide a method of inserting frusto-conical spinal fusion implants that includes spacing apart and supporting adjacent vertebrae;

It is still further another object of the present invention to provide a method for inserting frusto-conical spinal fusion implants that is consistent in use with the preservation of a uniform thickness of the subchondral vertebral bone;

It is another object of the present invention to provide a method for inserting frusto-conical spinal fusion implants having a shape which conforms to an easily produced complementary bore at the fusion site; and

It is a further object of the present invention to provide a method for inserting a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual heights of each implant.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of a frusto-conical spinal fusion implant having a body that is frusto-conical with an external thread having a substantially uniform radius.

Figure 1A is an enlarged fragmentary view along line 1A of Figure 1 illustrating the surface configuration of the implant of Figure 1.

Figure 3A is an alternative embodiment of the spinal fusion implant having a frusto-conical body with an external thread radius and thread height that are not constant.

Figure 3 is as cross sectional view along line 3--3 of the implant of Figure 3A.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant having a frusto-conical body and a surface configuration comprising ratchetings for engaging bone, with wells and channels for bone ingrowth.

Figure 5 is a cross sectional view along line 5--5 of the implant of Figure 4 illustrating the channels and wells of the implant.

Figure 6 is a cross sectional view along line 6--6 of the implant of Figure 4 illustrating the channels and wells of the implant.

Figure 6A is a side elevational view of an alternative embodiment of the spinal fusion implant having truncated sides forming a planar surface parallel to the longitudinal axis of the implant and ratchetings having a radius and height that are not constant.

Figure 6B is a top plan view of the spinal fusion implant shown in Figure 6A.

Figure 7 is a side elevational view in partial cut-away of an alternative embodiment of the spinal fusion implant having a body that is frusto-conical and a surface configuration comprising a plurality of spaced apart posts.

Figure 8 is a side elevational view of an alternative embodiment of the spinal fusion implant of Figure 1.

Figure 9 is a side elevational view and partial cut-away of a segment of the spinal column in lordosis showing the spinal fusion implant of Figure 8 being implanted with a driving instrument from the posterior approach to the spinal column.

Figure 10 is a side elevational view of an alternative embodiment of the spinal fusion implant having a frusto-conical body and truncated sides.

Figure 11 is an end view along line 11--11 of the spinal fusion implant of Figure 14 shown placed beside a second identical implant shown in hidden line.

Figure 12 is a side elevational view of an alternative embodiment of the spinal fusion implant having a body with an irregular configuration.

Figure 13 is a side elevational view of a segment of the spinal column partially in lordosis showing a first drill and a second drill used in the method of the present invention.

Figure 14 is a side elevational view of the spinal distractor instrument of the present invention.

Figure 15 is a top plan view of the spinal distractor instrument of Figure 14.

DETAILED DESCRIPTION OF THE DRAWINGS

The first part of the Detailed Description Of The Drawings is directed to the description of the structure of the frusto-conical implants inserted by the method of the present invention. The second part of the description of the drawings is directed to the method of the present invention.

Frusto-Conical Implants

Referring to Figure 1, a side elevational view of the spinal fusion implant for insertion with the method of the present invention generally referred to by numeral 20 is shown. The implant 20 has a body 22 that is frusto-conical in shape such that the body 22 has a diameter (root diameter) that is generally frusto-conical. The body 22 has an insertion end 24 and a trailing

end 26. The insertion end 24 may include a tapered portion 25 to facilitate insertion of the spinal implant 20. In the preferred embodiment, when the implant 20 is inserted from the anterior aspect of the spine, the body 22 of the implant 20 has a maximum diameter at a point nearest to the trailing end 26 and a minimum diameter at a point nearest to the insertion end 24.

The implant 20 has an external thread 28 having a substantially uniform radius R_1 measured from the central longitudinal axis L_1 of the implant 20. The outer locus of the external thread 28 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_1. While the major diameter of the implant 20 is substantially uniform, the external thread 28 may be modified at the leading edge by having initially a reduced thread radius to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 self-tapping. In the preferred embodiment, the external thread 28 has a first thread 30 of a lesser radius than the radius R_1 of the remainder of the external thread 28 to facilitate insertion of the implant 20. The second thread 32 has a greater radius than the first thread 30, but is still shorter than the radius R_1 of the remainder of the external thread 28 which is thereafter of constant radius.

The body 22 is frusto-conical substantially along the portion of the body 22 in contact with the adjacent vertebrae of the spine which allows for the creating and maintaining of the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The substantially uniform radius R_1 of the external thread 28 of the implant 20 allows for the engaging of the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the direction opposite to which the implant 20 was implanted. The greater thread height measured from the body 22 near the leading end 24 of the implant 20 provides greater purchase into the vertebral bone and again enhances the

stability of the implant 20. Further, the configuration of the external thread 28 increases the surface area of the implant 20 in contact with the vertebrae to promote bone ingrowth.

The implant 20 has a recessed slot 34 at its trailing end 26 for receiving and engaging insertion instrumentation for inserting the implant 20. The recessed slot 34 has a threaded opening 36 for threadably attaching the implant 20 to instrumentation used for inserting the implant 20.

Referring to Figure 1A, the implant 20 has an outer surface 38 that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer surface 38 is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. It is appreciated that the outer surface 38, and/or the entire implant 20, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant 20 may be further coated with bioactive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant 20 is shown as being solid, however it is appreciated that it can be made to be substantially hollow or hollow in part.

In the preferred embodiment, for use in the lumbar spine, the implant 20 has an overall length in the range of approximately 24 mm to 32 mm with 26 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-20 mm, with 14-16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 26 in the range of 10-24 mm, with 16-18 mm being the preferred diameter at the trailing end 26, when said implants are used in pairs. When used singly in the lumbar spine, the preferred diameters would be larger.

In the preferred embodiment, the implant 20 has a thread radius R_1 in the range of 6 mm to 12 mm, with 9-10 mm being the

preferred radius R_1. For use in the cervical spine, the implant 20 has an overall length in the range of approximately 10-22 mm, with 12-14 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-22 mm, with 16-18 mm being the preferred root diameter at the insertion end when used singly, and 8-10 mm when used in pairs. The body 22 of the implant 20 has a root diameter at the trailing end 26 in the range of 10-24 mm, with 18-20 mm being the preferred root diameter at the trailing end 26 when used singly, and 10-12 mm when used in pairs; a thread radius R_1 in the range of approximately 4-12 mm, with 9-10 mm being the preferred radius R_1 when inserted singularly and 5-7 mm when inserted side by side in pairs.

Referring to Figure 3, a cross sectional view along line 3--3 of the implant 120 is shown. The implant 120 has an outer wall 144 surrounding an internal chamber 146. The large and small openings 140 and 142 may pass through the outer wall 144 to communicate with the internal chamber 146. The internal chamber 146 may be filled with bone material or any natural or artificial bone growth material or fusion promoting material such that bone growth occurs from the vertebrae through the openings 140 and 142 to the material within internal chamber 146. While the openings 140 and 142 have been shown in the drawings as being circular, it is appreciated that the openings 140 and 142 may have any shape, size configuration or distribution, suitable for use in a spinal fusion implant without departing from the scope of the present invention.

The implant 120 has a cap 148 with a thread 150 that threadably attaches to the insertion end 124 of the spinal fusion implant 120. The cap 148 is removable to provide access to the internal chamber 146, such that the internal chamber 146 can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited

to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 148 and/or the spinal fusion implant 120 may be made of any material appropriate for human implantation including metals such as cobalt chrome, stainless steel, titanium, plastics, ceramics, composites and/or may be made of, and/or filled, and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. The cap 148 and the implant 120 may be partially or wholly bioabsorbable.

Referring to Figure 3A, an alternative embodiment of implant 120 is shown and generally referred to by the numeral 120'. The implant 120' has a body 122' similar to body 122 of implant 120 and has an external thread 128' having a radius R_3 measured from the central longitudinal axis L_3 of the implant 120'. The thread radius R_3 is not constant throughout the length of the implant 120' and the external thread 128' has a thread height that is also not constant with respect to the body 122' of the implant 120'. In the preferred embodiment, the implant 120' has an external thread 128' with a radius R_3 that increases in size from the insertion end 124' to the trailing end 126' of the implant 120'.

Referring to Figure 4, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 220. The implant 220 has a frusto-conical body 222 and an outer locus that is generally frusto-conical substantially along the portion of the implant 220 that is in contact with the adjacent vertebrae of the spine. The implant 220 has a surface configuration of forward facing ratchetings 240 suitable for engaging the bone of the adjacent vertebrae. Each of the plurality of ratchetings 240 has a bone engaging edge 242 and ramped portion 244. The ratchetings 240 have a radius R_4 measured from the central longitudinal axis L_4 of the implant 220 that increases from the insertion end 224 to the trailing end 226. The height of the ratchetings 240 measured from the body 222 is constant throughout the length of implant 220.

The orientation of the ratchetings 240 makes the insertion of the implant 220 easier than its removal, as the ramped portions 244 act as an inclined plane on the way in, while the bone engaging edges 242 resist motion in the opposite directions. These forward facing ratchetings 240 tend to urge the implant 220 forward until the unremoved bone of the vertebrae blocks further motion resulting in a very stable spine and implant construct.

In the preferred embodiment, the bone engaging edges 242 of the ratchetings 240 have a height at a highest point measured from the body 222 (root diameter) of the implant 220 in the range of 0.25 - 2.0 mm, with the preferred height being 0.4 mm for use in the cervical spine and 1.25 mm for use in the lumbar spine.

Referring to Figures 5 and 6, cross sectional views of implant 220 are shown. The implant 220 has channels 250 passing through the implant 220 and wells 260 formed in the surface of the implant 220. The wells 260 may or may not communicate with the channels 250. In the preferred embodiment of implant 220, the channels 250 have a diameter in the range of 0.1 mm to 6 mm, with 2-3 mm being the preferred diameter. The wells 260 have a diameter in the range of 0.1 mm to 6 mm, with 1-3 mm being the preferred diameter range. It is appreciated that although the channels 250 and wells 260 are shown having a generally rounded configuration, it is within the scope of the present invention that the channels 250 and wells 260 may have any size, shape, configuration, and distribution suitable for the intended purpose.

Referring to Figures 6A and 6B, an alternative embodiment of the implant 220 is shown and generally referred to by the numeral 220'. The implant 220' is similar in configuration to implant 220 and has ratchetings 240' having a radius R_s measured from the longitudinal central axis L_s that increases in size from the insertion end 224' to the trailing end 226'. The ratchetings 240' each have a height measured from the body 222' that is not constant throughout the length of the implant 220'. In the preferred embodiment, the ratchet radius R_s and the ratchet height increase in size from the insertion end 224' to the trailing end

226'.

As shown in Figure 6B, the implant 220' has truncated sides 270 and 272 forming two planar surfaces which are diametrically opposite and are parallel to the longitudinal axis L_4. In this manner, two implants 220' may be placed side by side with one of the sides 270 or 272 of each implant touching, such that the area of contact with the bone of the adjacent vertebrae and the ratchetings 240' is maximized. Alternatively, the implant 220' may have one truncated side.

Referring to Figure 7, a side elevational view in partial cut-away of an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 420. The implant 420 has a body 422 that is frusto-conical in shape substantially along the portion of the implant 420 that is in contact with the adjacent vertebrae of the spine and has an insertion end 424 and a trailing end 426. The implant 420 has an outer surface 438 that is capable of receiving and holding bone, or other materials capable of participating in the fusion process and/or capable of promoting bone ingrowth. In the preferred embodiment, the surface 438 comprises a plurality of posts 440 that are spaced apart to provide a plurality of interstices 442 which are partial wells with incomplete walls capable of holding and retaining milled bone material or any artificial bone ingrowth promoting material. The implant 420 may be prepared for implantation by grouting or otherwise coating the surface 438 with the appropriate fusion promoting substances.

Referring to Figure 8, a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention generally referred to by numeral 520 is shown. The implant 520 has a body 522 having a root diameter that is frusto-conical in the reverse direction as that of implant 20 shown in Figure 1, in order to preserve and/or restore lordosis in a segment of spinal column when inserted from the posterior aspect of the spine. The body 522 has an insertion end 524 and a trailing end 526. In the preferred embodiment, the body 522 of the implant 520

has a minimum diameter at a point nearest to the trailing end 526 and a maximum diameter at a point nearest to the insertion end 524. The insertion end 524 may have an anterior nose cone portion 530 presenting a tapered end to facilitate insertion.

The implant 520 has an external thread 528 having a substantially uniform radius R_6 measured from the central longitudinal axis L_6 of the implant 520, such that the external diameter of the external thread 528 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_6. It is appreciated that the thread 528 can have a major diameter that varies with respect to the longitudinal axis L_6, such that the major diameter may increase from the insertion end 524 to the trailing end 526 or the reverse. The external thread 528 has a thread height measured from the body 522 that increases from the insertion end 524 to the trailing end 526.

Referring to Figure 9, a segment of the spinal column S is shown with the vertebrae V_1 and V_2 in lordosis and an implant 520 shown being inserted from the posterior aspect of the spinal column S with an instrument driver D. The implant 520 is inserted with the larger diameter insertion end 524 first in order to in initially distract apart the vertebrae V_1 and V_2 which then angle toward each other posteriorly as the implant 520 is fully inserted. It is appreciated that the insertion of implant 520 does not require the adjacent vertebrae V_1 and V_2 to be placed in lordosis prior to insertion, as the full insertion of the implant 520 itself is capable of creating the desired lordotic angular relationship of the two vertebrae V_1 and V_2.

In the preferred embodiment of implant 520, for use in said lumbar spine, the implant 520 has an overall length in the range of approximately 24 mm to 30 mm, with 26 mm being the preferred length. The body 522 of the implant 520 has a root diameter at the insertion end 524 in the range of 12-22 mm, with 16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 526 in the range of 10-20 mm, with 14 mm being the preferred diameter at the trailing end 526.

In the preferred embodiment, the implant 520 has a thread radius R_6 in the range of 6 mm to 12 mm, with 8 mm being the preferred radius R_6.

Referring to Figure 10, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 620 and a partial fragmentary view of a second identical implant, generally referred to by the numeral 621 are shown. The implant 620 has a body 622 that is partially frusto-conical in shape similar to body 22 of implant 20 shown in Figure 1, and has an insertion end 624 and a trailing end 626. The body 622 of the implant 620 has truncated sides 670 and 672 forming planar surfaces that are parallel to the longitudinal axis L_7. In this manner, two implants 620 and 621 may be placed side by side, with one of the sides 670 or 672 of each implant with little space between them, such that the area of contact with the bone of the adjacent vertebrae is maximized. It is appreciated that the body 622 may also be cylindrical in shape and have truncated sides 670 and 672.

The implant 620 has an external thread 628 having a radius R_6 measured from the central longitudinal axis L_7 that may be constant, such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially cylindrical. It is appreciated that the external thread 628 may have a thread radius R_7 that is variable with respect to the longitudinal axis L_7 such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially frusto-conical.

Referring to Figure 11, an end view of the implant 620 placed beside implant 621 is shown. The implant 620 has a thread radius that is substantially constant and has a thread height measured from the body 622 that is greater at the sides 670 and 672. In this manner, two implants 620 and 621 can be placed beside each other with the external thread 628 of each implant interdigitated allowing for closer adjacent placement of the two implants as a result of the substantial overlap of the external

thread 628 at the side 670 or 672 of the implants.

Referring to Figure 12, an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 700. The implant 700 is similar in configuration to implant 20 shown in Figure 1, except that the body 722 has an irregular configuration. The configuration of the body 722 has a root diameter D which is variable in size throughout the length of the implant 700 and, as shown in this embodiment, comprises larger diameter portions 750 and smaller diameter portions 752. It is appreciated that each of the large diameter portions 750 may be of the same or different diameter and each of the smaller diameter portions 752 may be of the same or different diameter.

The outer surface of the body 722 of implant 720 may be filled with fusion promoting substances such that the smaller diameter portions 752 may hold such fusion promoting substances. If so filled, the composite of the implant 700 and the fusion promoting material could still produce an even external surface of the body 722 if so desired.

The Method Of The Present Invention

The embodiments of the frusto-conical implants of the present invention described above may be implanted with the method of the present invention described below.

In the preferred method of the present invention, the diseased disc between two vertebrae is at least partially removed from the anterior aspect of the spine. The two vertebrae adjacent the diseased disc are then optimally distracted and placed in the desired amount of lordosis by any of a number of well known means including, but not limited to, those means that distract the vertebral bodies by engaging screws placed into the anterior aspect of the vertebral bodies, and disc space distractors that are placed from the anterior aspect of the spine into the disc space and are then used to urge the vertebral endplates away from each other and into lordosis. When the correct amount of distraction and lordosis have been achieved at the affected disc level, then a frusto-

conical space is created from anterior to posterior between the adjacent vertebrae. The frusto-conical space that is created is greater in diameter than the disc space height, such that some bone is removed from each of the adjacent vertebrae. The created space is generally frusto-conical in shape, being greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

It should be noted that where the spine is of sufficient width, it may be possible to prepare two such frusto-conical spaces side-by-side at the same disc level, allowing for the use of two implants instead of one. In either event, once the frusto-conical space is prepared and all debris removed, the implant is then inserted into the prepared space across the disc space, penetrating into each of the adjacent vertebrae, from anterior to posterior.

In the preferred embodiment, the diseased disc is first removed by conventional discectomy. The depth of the disc space is then determined by direct measurement. An interspace distractor such as that described by Michelson in U.S. Patent Application Serial No. 08/396,414 entitled Apparatus and Method of Inserting Spinal Implants, incorporated herein by reference, is then inserted into the disc space. A series of such distractors are available and are sequentially inserted until the optimal amount of distraction across the disc space is achieved. The interspace distractors utilized for this purpose are wedged so as to induce physiological lordosis. An outer sleeve is then fitted over the barrel portion of the interspace distractor and firmly seated in engagement with the spine. As previously described in U.S. Patent Application Serial No. 08/396,414, said outer sleeve may itself have extended portions capable of either maintaining or of obtaining and maintaining distraction. Said outer sleeve may also have vertebrae engaging prongs to further stabilize the outer sleeve to the spine and to more rigidly control motion at the adjacent vertebrae. As described in U.S. Patent Application Serial No. 08/396,414, the use of the extended outer sleeve with distractor portions actually makes it possible to achieve the optimal distraction and lordosis without the use of the described

interspace distractor. However, if the interspace distractor is used, then the outer sleeve is fully engaged to the spine, the distractor is removed, and in the preferred method by use of a slap-hammer, engaging the most proximal aspect of the distractor.

Referring to Figure 13, a segment of the spinal column S is shown with vertebrae V_1 and V_2 shown in lordosis adjacent to disc space D_1 and vertebrae V_2 and V_3 shown not in lordosis, but relatively parallel to each other adjacent disc space D_2. A first drill 810 making an opening 812 across the disc space D_1, and into adjacent vertebrae V_1 and V_2, and a second drill 820 making an opening 822 across the disc space D_2 and into adjacent vertebrae V_2 and V_3 are shown in Figure 13. In the preferred embodiment, the interbody spinal fusion implant itself is threaded and frusto-conical in shape and therefore, the remaining portion of the procedure will be described in regard to that particular embodiment of the present invention, by way of example. With the disc space fully distracted and in anatomical lordosis and with the outer sleeve firmly engaged to the spine, it is then desirable to prepare the spine for receipt of the interbody fusion implant. It is preferable to prepare a space across the disc space and penetrating into the adjacent vertebrae which space corresponds roughly to the root dimensions of the implant to be implanted. For this purpose, a stopped-out bone cutting instrument is inserted through the outer sleeve, the shape of the cutting portion of the first drill 510 generally corresponding to the frusto-conical shape of the root diameter of the implant being inserted. This instrument may take the form of a frusto-conical drill or a mill and may be used to cut the bone by rotation, said rotation being achieved either through a manual handle or with power. Having prepared the space, the surgeon has two options. One is to remove the outer sleeve and then, because the implant is itself frusto-conical, screw the implant in using an implant driver capable of locking to the implant. The other is to leave the outer sleeve in place during the insertion of the implant.

If per the above, the surgeon wishes to remove the outer

sleeve, the insertion of the implant itself causes a reproduction of the previous distraction which is easily achieved as the implant itself is frusto-conical in shape and the space created by the removal of the bone to either side of the disc space essentially corresponds to the root diameter of the implant such that as the implant is inserted, the threads are embedded into the vertebrae adjacent the disc space. Once the implant is fully inserted, the insertion apparatus is disconnected from the implant. If the cervical disc space is sufficiently wide from side-to-side, the procedure is performed in the same manner except that either a double-barrelled outer sleeve may be used or the previously described procedure essentially performed twice at the same disc level, such that a pair of implants may be inserted side-by-side.

In the alternative, if the surgeon wishes to leave the outer sleeve in place during the insertion of the implant and if the implant, as per this example has both a minor and a major diameter such as with a threaded implant, then the bone removing portion of the drilling means needs to generally correspond to the root diameter of the implant while the inside diameter of the outer sleeve needs to be great enough to allow the passage of the major diameter of the implant. It is desirable to stabilize the bone removal instrument and to assure that it removes equal portions of bone from each of the adjacent vertebrae. This may be achieved by a reduction sleeve which fits between the bone removal means and the inner wall of the outer sleeve and which essentially corresponds to the difference between the minor and major diameters of the implant, or some portion of the drill shaft proximal to the cutting end may have a diameter which corresponds to the major diameter of the implant even while the distal bone removing portion corresponds to the root diameter of the implant. In either way, the bone removal instrument is both stabilized and centered within the outer sleeve.

The approach to the lumbar spine may either be retroperitoneal, or transperitoneal. The procedure may be performed under direct vision, or laproscopically with the use of

an endoscope. Generally it is preferable to utilize two implants which are inserted in an anterior to posterior direction, one to either side of the midline. The implants may be inserted using either a single-barrelled or double-barrelled outer sleeve, and by the methods previously described in the pending U.S. Patent Application Serial No. 08/396,414 from which the present methods differ only in the shape of the drill end or bone milling device which is essentially conical. As also previously described, in co-pending application Serial No. 08/396,414, the methods can be utilized for the insertion of non-threaded implants in which case said implants are linearly advanced rather than threaded in. And finally, as previously described in co-pending application 08/390,131, the implants themselves may have truncations on the sides to form a planar surface parallel to the longitudinal axis of the implant, such that it is possible to fit two such implants more closely together by narrowing the width of each while preserving their height. As taught in copending Application Serial No. 08/396,414, a tap may be used after the drilling step and prior to the insertion of the implants.

Referring again to Figure 13, in an alternative method of implant insertion, the use of at least partially frusto-conical interbody spinal fusion implants allows for the creation of lordosis by the implant itself where none is present to begin with as with the angular relationship of V_2 and V_3 shown in Figure 13. As per this example, the disc space D_2 which in the preferred circumstance would be fully distracted but need not be, but lacking lordosis, could have a bore drilled across that space such that equal arcs of bone A_1 and A_2 are removed from each of the adjacent vertebrae V_2 and V_3 using a drill 820 or bone milling device capable of producing a cylindrical bore. Where one such boring is performed, it would generally be in the center line and directed from anterior to posterior. This might be appropriate for use in the cervical spine. More commonly and as generally would be the rule in the lumbar spine, a pair of bores would be so created from anterior to posterior, one to each side of the midline. The

essential feature here is that the vertebrae V_2 and V_3, whether distracted from each other or not, are essentially lacking the full restoration of lordosis. The use of the substantially cylindrical bone drill 820 provides for the removal of a generally uniform thickness of bone from each of the adjacent vertebrae from anterior to posterior. The insertion of a frusto-conical implant, having a larger diameter at its trailing edge than at its leading edge, then forces the anterior aspects of the adjacent vertebrae apart more so than the posterior aspects where the diameter is lesser. This utilizes the implant to produce the desired lordosis.

The method for the insertion of the spinal fusion implants of the present invention from the posterior aspect of the spine is described in detail in co-pending patent Application Serial No. 08/396,414 and is incorporated herein by reference. Further, in the method of inserting the implants of the present invention from the posterior aspect of the spine, it is possible to place the adjacent vertebrae in lordosis prior to the bone removal step.

Referring to Figures 14 and 15, spinal distractor 900 is shown which is used for distracting the adjacent vertebrae in lordosis prior to the bone removal step. The spinal distractor 900 has a tapered insertion end 902 to facilitate insertion, an instrument engaging end 904, and top and bottom surfaces 906 and 908. The top and bottom surfaces 906 and 908 are in a angular relationship to each other and are furthest apart at a point near the insertion end 902 to produce the desired lordosis when inserted in the disc space between two adjacent vertebrae. The top and bottom surfaces 906 and 908 have surface roughenings 910 for engaging the bone of the adjacent vertebrae and stabilizing the spinal distractor 900 when inserted.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described

in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

Each of the features disclosed in the various embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.

What is claimed is:

1. A method for inserting at least one frusto-conical spinal fusion implant made of a material appropriate for human implantation, said implant having bone engaging means for engaging the adjacent vertebrae in a segment of the spinal column, comprising the steps of:

distracting the two vertebrae adjacent the diseased disc and placing the two vertebrae in the desired amount of lordosis;

drilling a frusto-conical recipient bore across the disc space and into the adjacent vertebrae, said bore being at least in part greater in diameter than the disc space height such that some bone is removed from each of the adjacent vertebrae; and

inserting a frusto-conical spinal fusion implant into said recipient bore.

2. The method claim 1 in which said bore is greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

3. The method claim 1 in which said bore is substantially cylindrical.

4. The method of claim 1 in which said step of drilling includes the use of a drill having a substantially frusto-conical shaped bone removing means.

5. The method of claim 1 in which a second spinal fusion is implanted across the disc space engaging each of the adjacent vertebrae side by side and adjacent to said first spinal fusion implant.

6. The method of claim 5 comprising the step of drilling a second recipient bore across the disc space partially overlapping said first bore, the combined width of said first and second recipient bores being less than the sum of the individual diameters of said first and second recipient bores; and inserting a second spinal

fusion implant.

7. The method of claim 1 in which said method is performed from the anterior aspect of the spinal column.

8. The method of claim 1 in which said method is performed from the posterior aspect of the spinal column.

9. The method of claim 1 in which the step of drilling said recipient bore includes the removal of a portion of bone parallel to the endplates of said adjacent vertebrae.

10. A method for inserting at least one frusto-conical spinal fusion implant made of a material appropriate for human implantation, said implant having bone engaging means for engaging the adjacent vertebrae in a segment of the spinal column, comprising the steps of:

distracting the two vertebrae adjacent the diseased disc;

drilling a recipient bore across the disc space and into the adjacent vertebrae, said bore being at least in part greater in diameter than the disc space height such that some bone is removed from each of the adjacent vertebrae; and

inserting a frusto-conical spinal fusion implant into said recipient bore.

11. The method of claim 10 in which said recipient bore is generally cylindrical in shape.

12. The method of claim 10 in which said step of drilling includes the use of a drill having a substantially cylindrical shaped bone removing means.

13. The method of claim 10 in which a second spinal fusion is implanted across the disc space engaging each of the adjacent vertebrae side by side and adjacent to said first spinal fusion

implant.

14. The method of claim 13 comprising the step of drilling a second recipient bore across he disc space partially overlapping said first bore, the combined width of said first and second recipient bores being less than the sum of the individual diameters of said first and second recipient bores; and inserting a second spinal fusion implant.

15. The method of claim 10 in which said method is performed from the anterior aspect of the spinal column.

16. The method of claim 10 in which said method is performed from the posterior aspect of the spinal column.

17. The method of claim 10 in which the step of drilling said recipient bore includes the removal of a portion of bone parallel to the endplates of said adjacent vertebrae.

ABSTRACT

The present invention is directed to a method of inserting a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration and the instrumentation and methods by which the implants.

FIG. 1

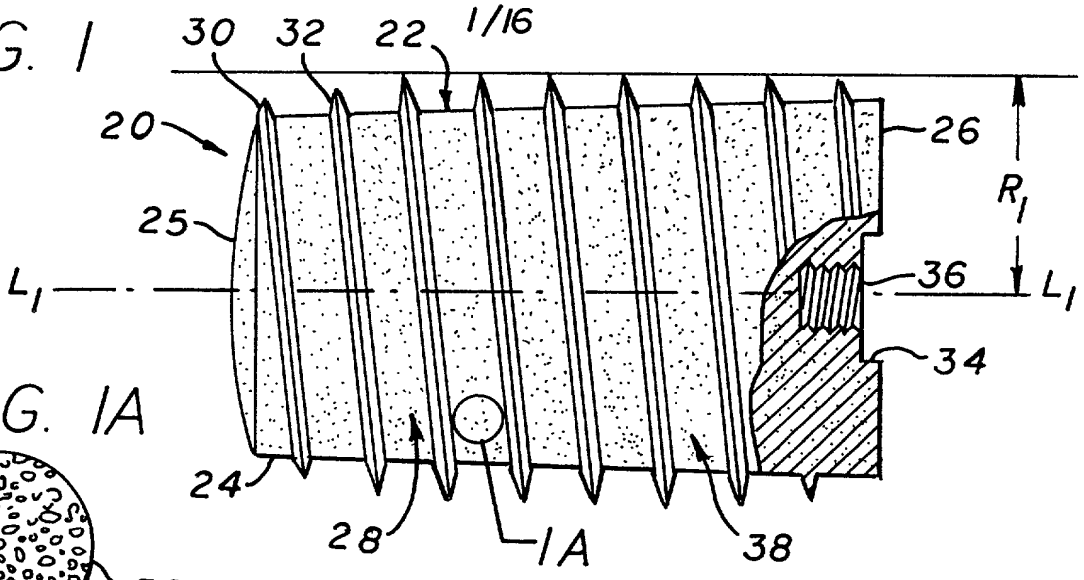


FIG. 1A

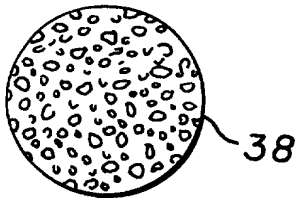


FIG. 2

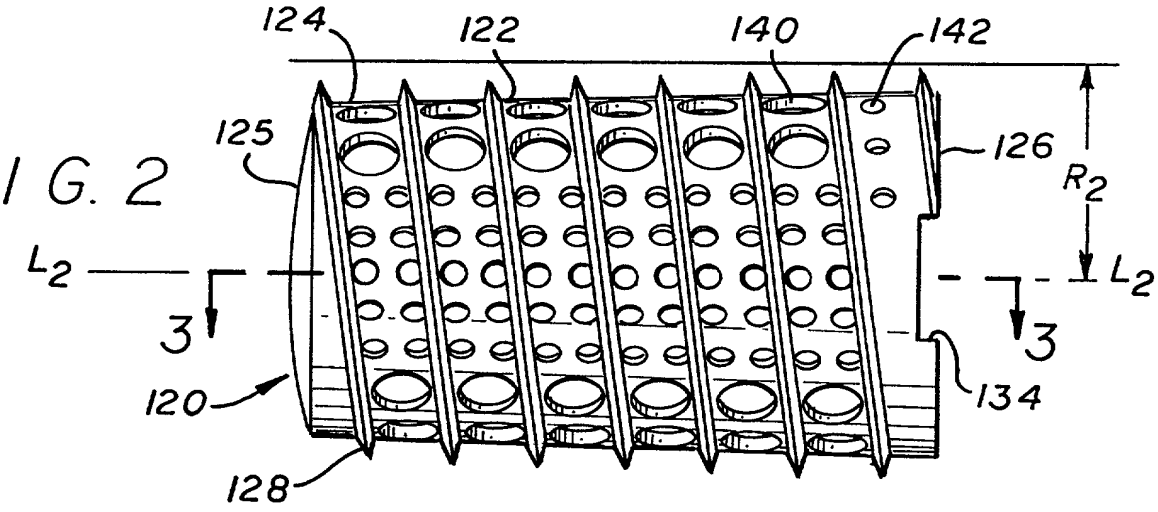


FIG. 3

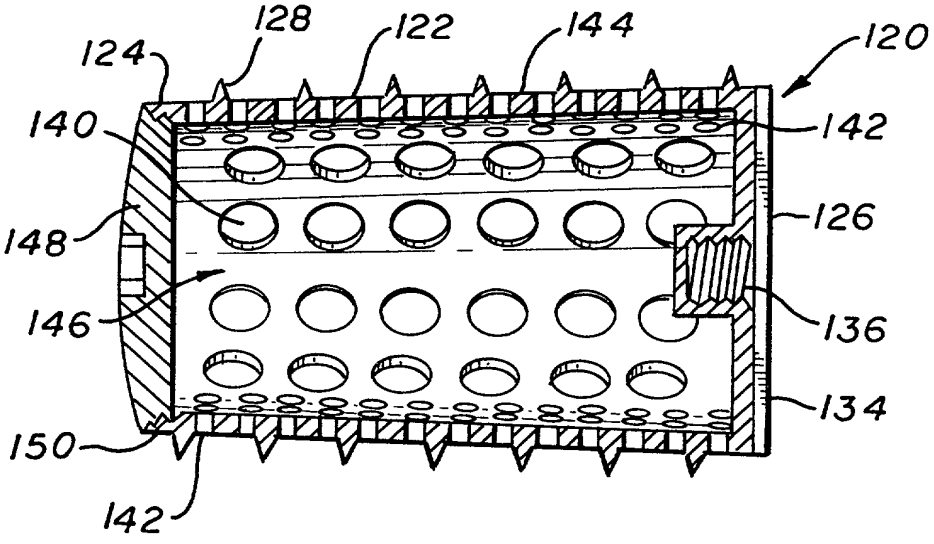


FIG. 3A

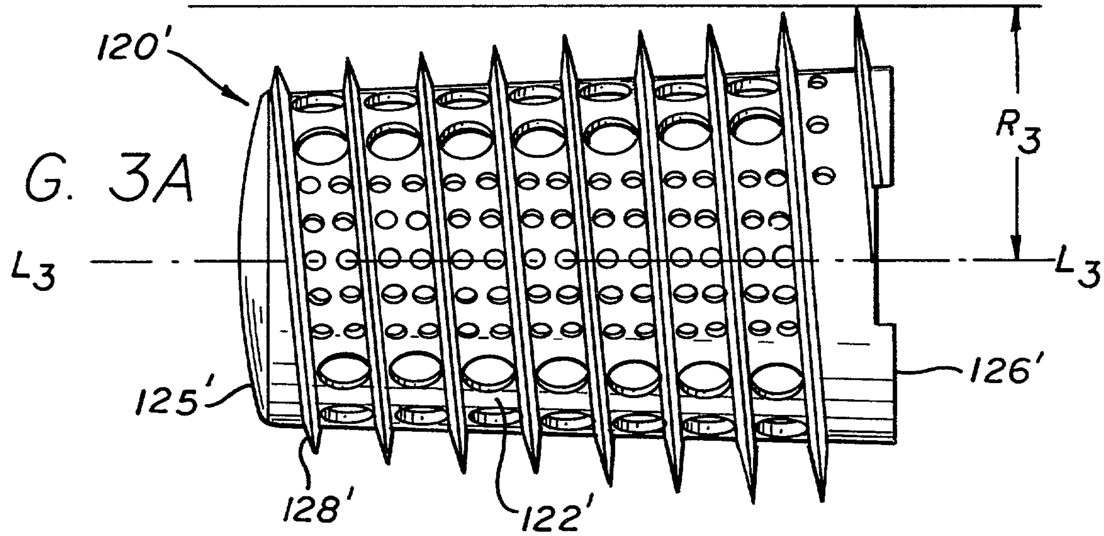


FIG. 4

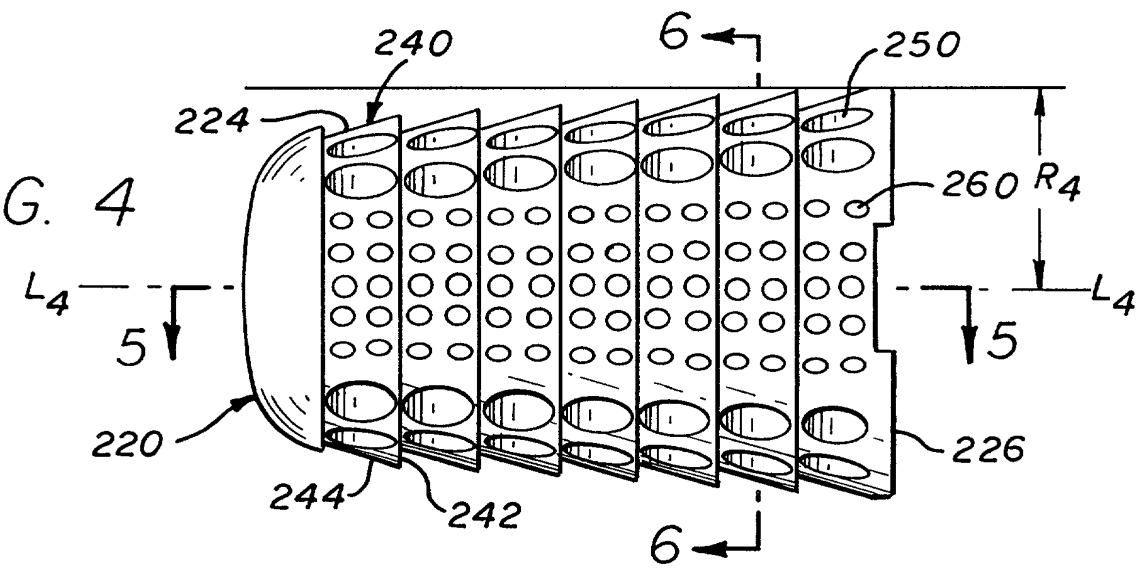
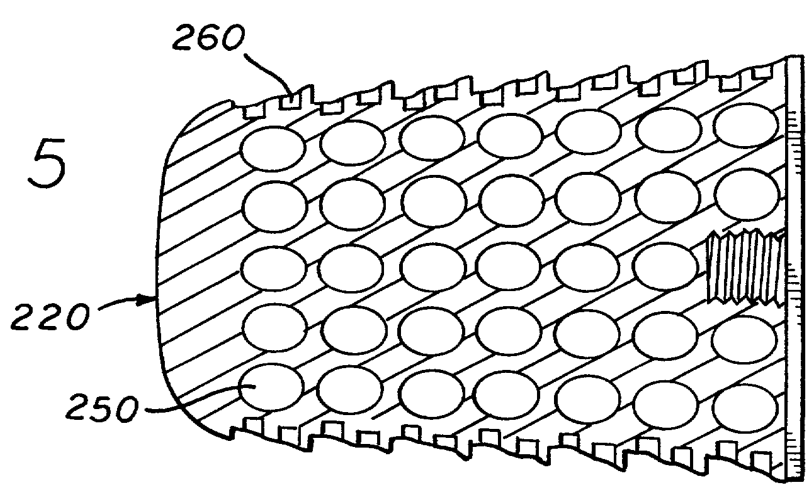
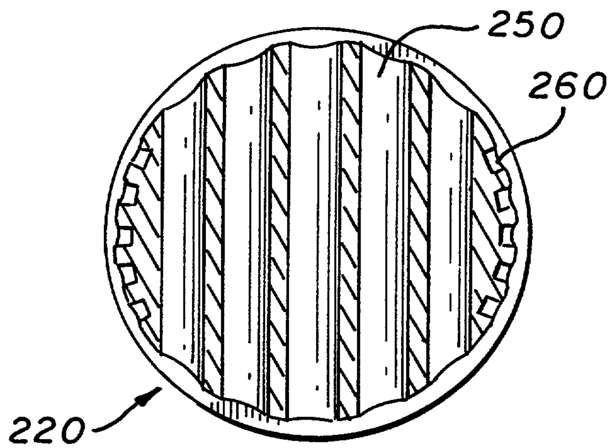


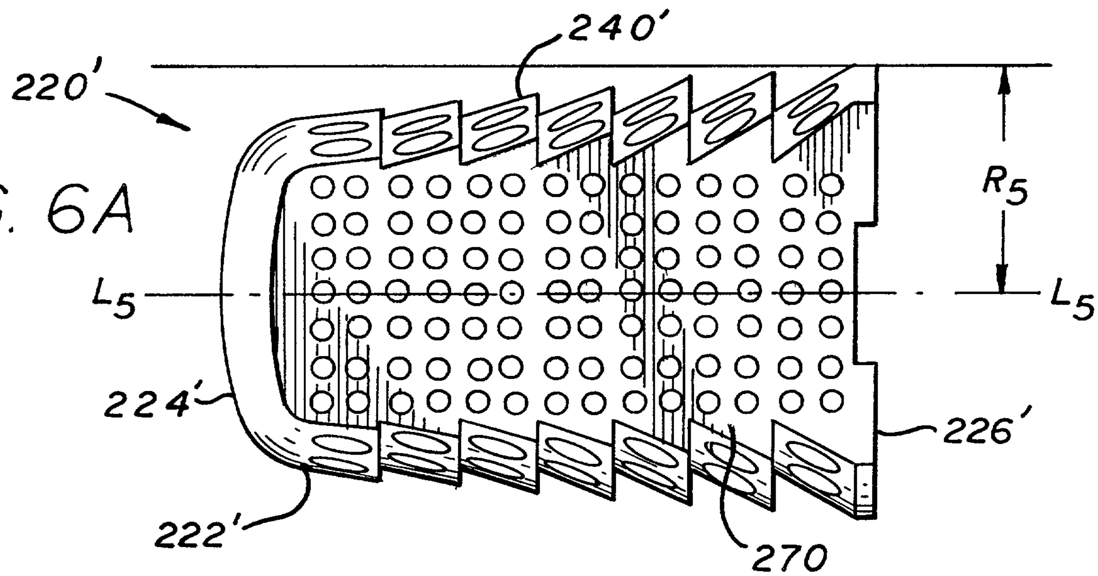
FIG. 5



F I G. 6



F I G. 6A



F I G. 6B

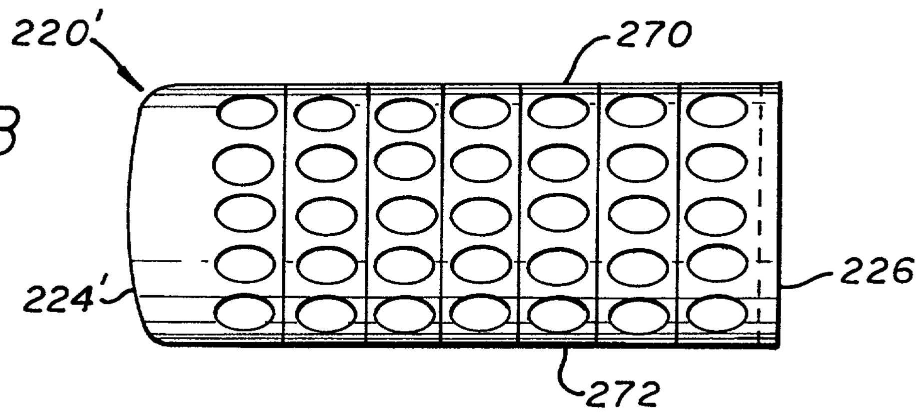


FIG. 7

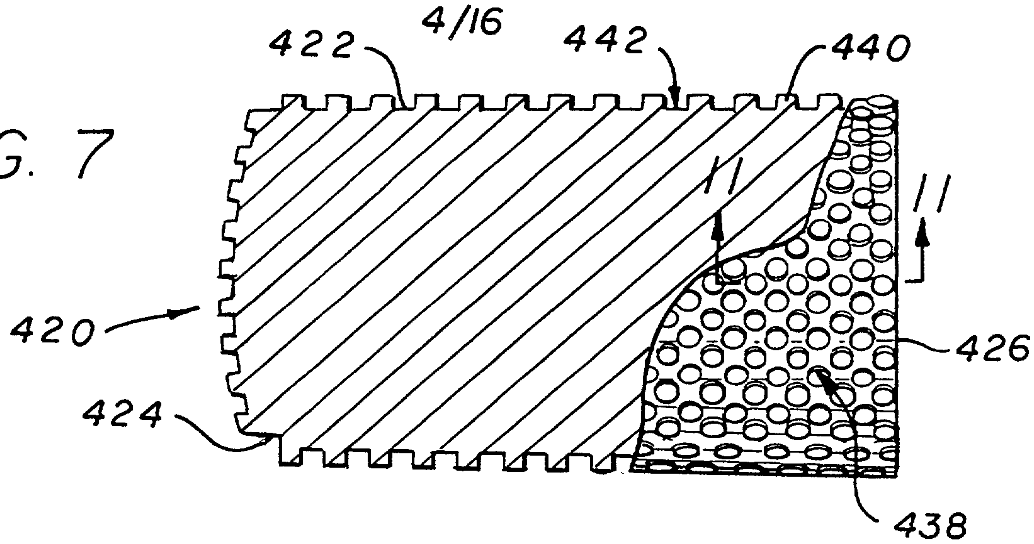


FIG. 8

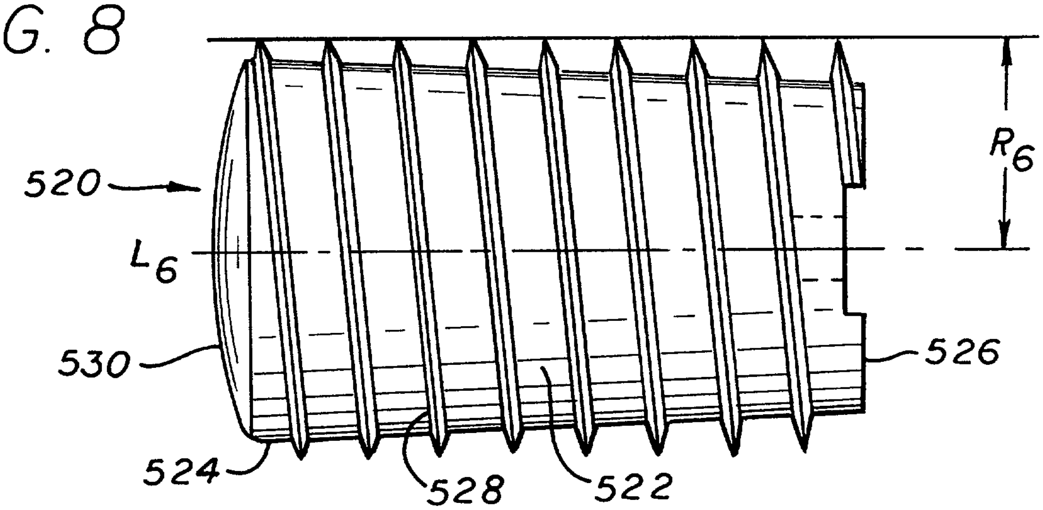


FIG. 10

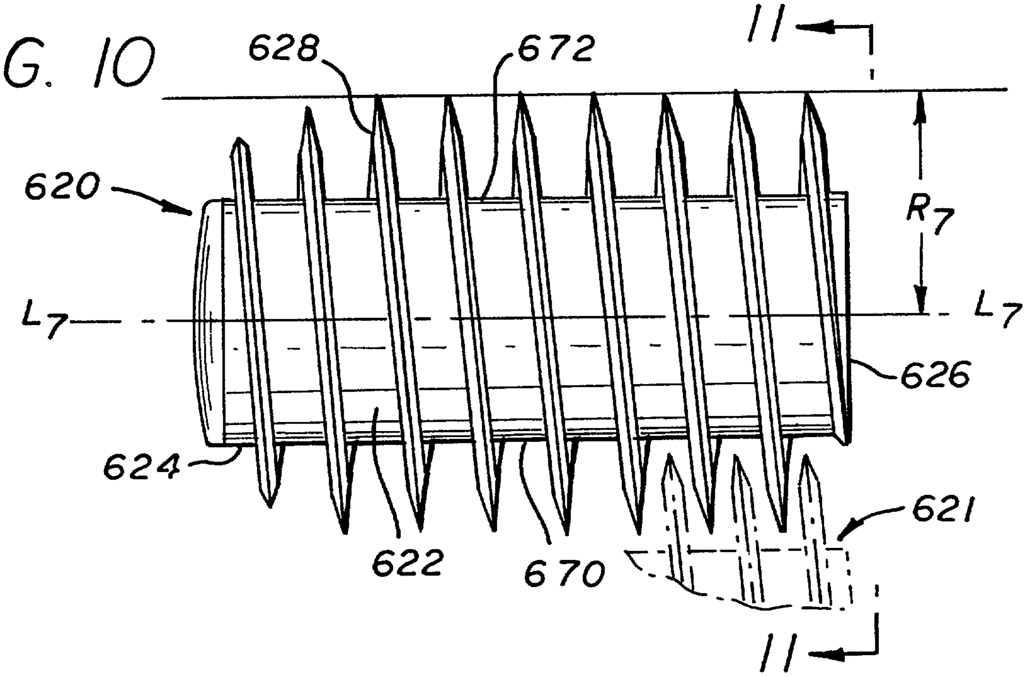


FIG. 9

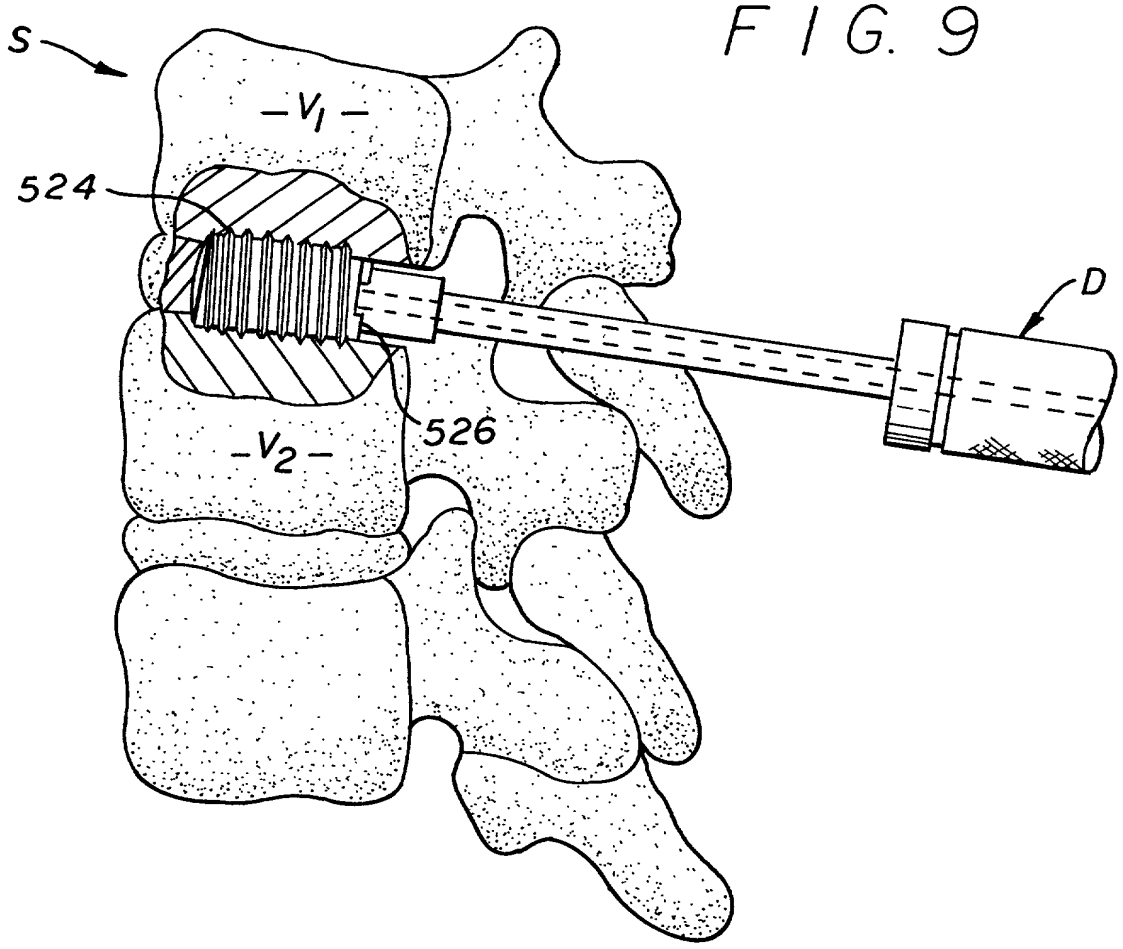


FIG. 11

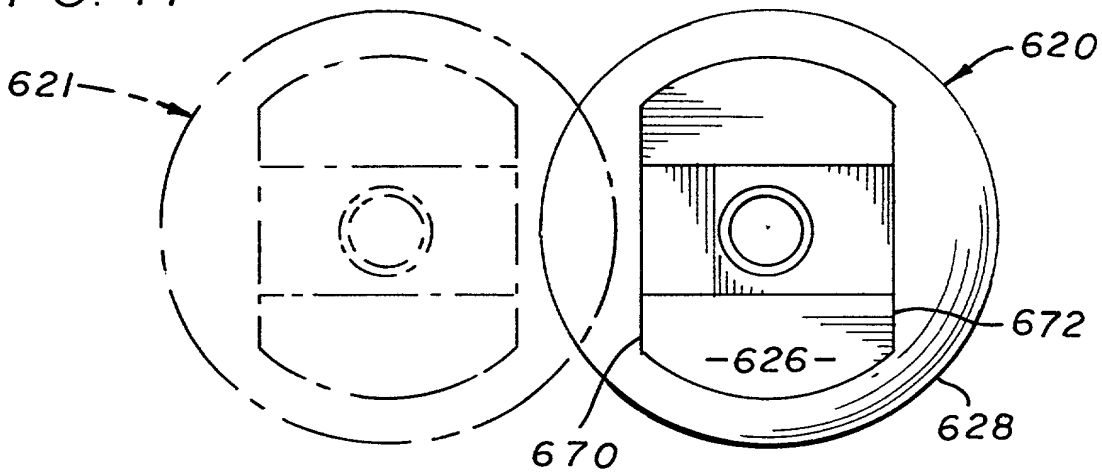


FIG. 13

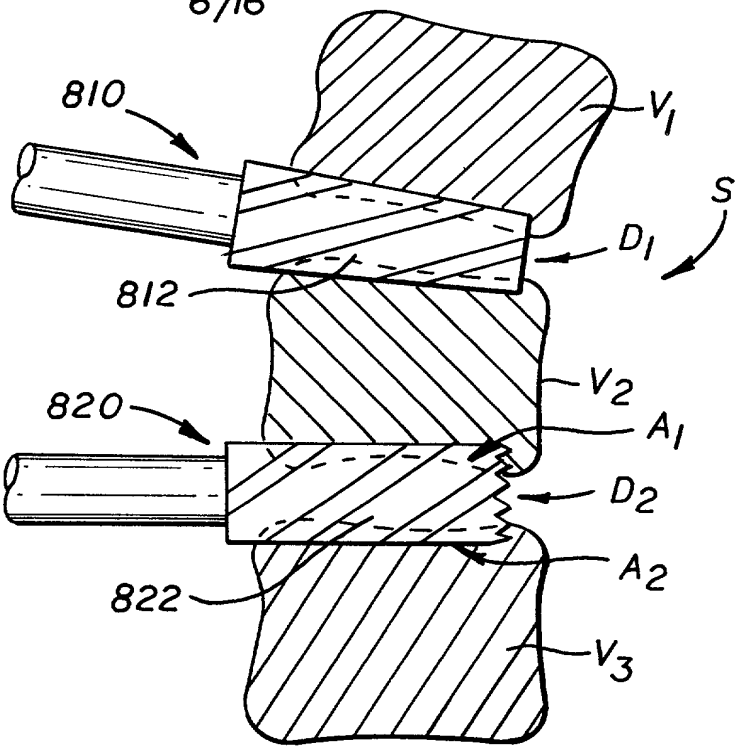


FIG. 14

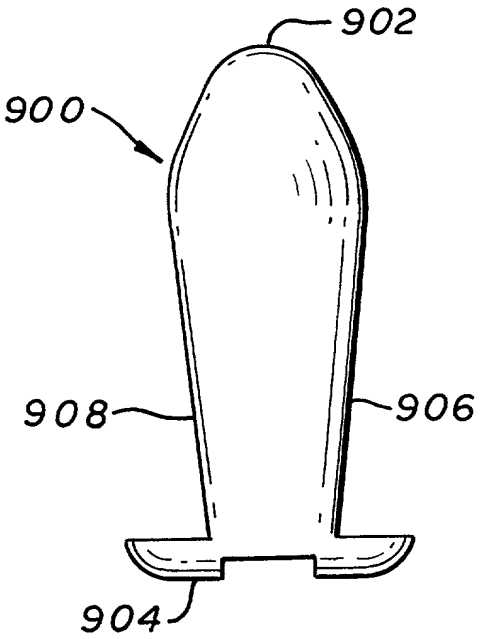
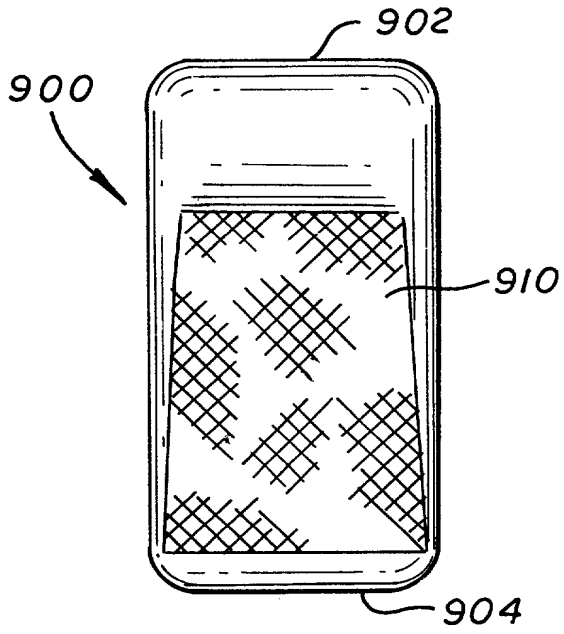


FIG. 15



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

English Language Declaration

As a below named Inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name,

I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the inventive design entitled

METHOD FOR INSERTING FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS

the specification of which

(mark one)

XXX is attached hereto or enclosed herewith.

_____ was filed on _____ as

Application Serial No. _____

_____

and was amended on _____

_____. (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose Information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 or §172 of any foreign application(s) for patent or Inventor's certificate listed below and have also identified below any foreign application for patent or Inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner

English Language Declaration

provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

08/396,414 (Application Serial No.)	02/27/95 (Filing Date)	Pending (Status: patented, pending, abandoned, etc.)
08/074,781 (Application Serial No.)	06/10/93 (Filing Date)	Pending (Status: patented, pending, abandoned, etc.)
07/698,674 (Application Serial No.)	05/10/91 (Filing Date)	Abandoned (Status: patented, pending, abandoned, etc.)
07/205,935 (Application Serial No.)	06/13/88 (Filing Date)	Patented (Status: patented, pending, abandoned, etc.)
08/390,131 (Application Serial No.)	02/17/95 (Filing Date)	Pending (Status: patented, pending, abandoned, etc.)
29/023,633 (Application Serial No.)	10/03/94 (Filing Date)	Pending (Status: patented, pending, abandoned, etc.)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United states Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint **Lewis Anten, Registration Number 26,604 and Amedeo Ferraro, Reg. No. 37,129** to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. Please send all correspondence, transmit all faxes, and direct all telephone calls to:

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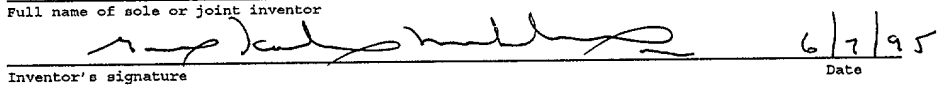
GARY KARLIN MICHELSON, M.D.
Full name of sole or joint inventor



Inventor's signature

6/7/95
Date

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Venice, California 90291
Post Office Address

APPLICATION FOR LETTERS PATENT

BY

GARY KARLIN MICHELSON, M.D.

FOR

METHOD FOR INSERTING

FRUSTO-CONICAL INTERBODY

SPINAL FUSION IMPLANTS

CERTIFICATE OF EXPRESS MAILING

"Express Mail"
Mailing Label No. EG910183965US

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PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231.

Date of Deposit: June 7, 1995

Signed: Roseanne Becker

Typed or
Printed Name: Roseanne Becker

Date: June 7, 1995